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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-0263; Docket No. CDC-2019-0110]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Requirements for the Importation of Nonhuman Primates into the United States. This information collection contains the reporting and documentation requirements for registered importers of nonhuman primates, as outlined in 42 Code of Federal Regulations part 71.53 Requirements for importers of nonhuman primates.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0110 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74,

Atlanta, Georgia 30329; phone: 404-639-7570; E-mail:
omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Requirements for the Importation of Nonhuman Primates into the United States (OMB Control No. 0920-0263, Exp. 08/31/2020) - Revision - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) .

Background and Brief Description

Under the 42 CFR 71.53, CDC collects information pertaining to importers and imported nonhuman primates. This information collection enables CDC to evaluate compliance with pre-arrival

of shipment notification requirements, to investigate the number and species of imported nonhuman primates, and to determine if adequate measures are being taken for the prevention of exposure to persons and animals during importation.

Since May 1990, CDC has monitored the arrival and/or uncrating of certain shipments of non-human primates imported in to the United States. In February 2013, CDC promulgated two regulations pertaining to the importation of nonhuman primates. The first rule, Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples, outlines a process by which importers can send liver tissues to CDC from primates that die during importation from reasons other than trauma (2/12/2013, Vol.78, No. 29, p.9828). CDC performs these tests due to the absence of a private sector option. The second rule, Requirements for Importers of Nonhuman Primates, consolidates into 42 CFR 71.53 the requirements previously found in 42 CFR part 71.53 with those found in the Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States (2/15/2013, Vol. 78, No. 32 /p. 11522). It also rescinded the six-month special-permit requirements for cynomolgus, African green, and rhesus monkeys and extended the time period for registration/permit renewal from 180 days to two years, reducing much of the respondent burden. CDC feels these regulatory changes and reporting requirements balance the public

health risks posed by the importation of nonhuman primates with the burden imposed on regulating their importation.

All registered importers of non-human primates are required by 42 CFR Part 71.53 to maintain certain disease control procedures and keep certain records. Standard business practices likely dictate that importers already keep records on the origin, transportation, and disposition of the nonhuman primates. Thus, CDC asks for information which should already be maintained by the importers and need only be assembled and reported. The estimate of burden hours and costs reflects assembling and reporting only. CDC requests approval for an estimated 185 annual burden hours. There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name/CFR Reference	# of Respondents	# of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (New Importer)	1	1	10/60	1

Nonhuman Primate Importer	CDC 75.10A Application for Registration as an Importer of Nonhuman Primates (Re-Registration)	12	1	10/60	2
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (New Importer)	1	1	10	10
Nonhuman Primate Importer	71.53(g)(1)(iii) and (h) Documentation and Standard Operating Procedures (no form) (Registered Importer)	12	1	30/60	6
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n)	25	6	15/60	38

	(no form)				
Nonhuman Primate Importer	Statements regarding the health of the nonhuman primates during travel and CDC quarantine (42 CFR 71.53 (m) (no form)	25	6	15/60	38
Nonhuman Primate Importer	Statements , including necropsy reports, about the nonhuman primates upon their release from CDC quarantine . (42 CFR 71.53 (m) (n o form)	25	3	15/60	19
Nonhuman Primate Importer	Quarantine release 71.53 (l) (n o form)	25	6	15/60	38
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials	10	10	20/60	33
Total					185

Jeffrey M. Zirger,

Lead,

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Centers for Disease Control and Prevention.

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